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EXAMINER

LILLING, HERBERT J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,569

Applicant(s)

SAWADA ET AL.

Examiner

HERBERT J. LILLING

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1-22-02; 4-12-02; 1-27-03; 3-28-03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- ☐ Interview Summary (PTO-413) Paper No(s). _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Art Unit: 1651

1. Receipt is acknowledged of the prior art information disclosure statements filed January 22, 2002, April 12, 2002, January 27, 2003 and March 28, 2003 plus the priority papers filed January 22, 2002.

2. Claims 1-19 are pending in this application/

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, drawn to the first product which is a yeast belonging to *Issatchenkia*.

Group II, claim(s) 1, drawn to the second product which is a yeast belonging to *Hanseniaspora*.

Group III, claim 1, drawn to the third product which is a yeast belonging to *Kloeckera*.

Group IV, claim 1, drawn to the fourth product which is a yeast belonging to *Kluyveromyces*.

Group V, claim 1, drawn to the fifth product which is a yeast belonging to *Pichia*.

Group VI, claim 1, drawn to the sixth product which is a yeast belonging to *Torulaspora*.

If there are more than one yeast employed, applicant is entitled to elect the combination of the above as noted by the elected groups above.

Claim 2 will be examined with the elected Group pertaining to the yeast(s).

Claim 3 will be examined with the elected Group pertaining to the yeast(s).

Claims 15 and 16 will be examined with the elected Group pertaining to the yeast(s).

Art Unit: 1651

Group VII, claim 4, drawn to a secondary bile acid production inhibitor containing a yeast .

Group VIII, claim(s) 5, drawn to a product which is a secondary bile acid production inhibitor containing a yeast belonging to :

Issatchenkia

Group IX, claim(s) 5, drawn to a product which is a secondary bile acid production inhibitor containing a yeast belonging to

Hanseniaspora.

Group X, claim 5, drawn to a product which is a yeast belonging to Kloeckera.

Group XI, claim 5, drawn to a product which is a yeast belonging to Kluyveromyces.

Group XII, claim 5, drawn to a product which is a yeast belonging to Pichia.

Group XIII, claim 5, drawn to a product which is a yeast belonging to Torulaspora.

Claim 6 will be examined with the elected Group VIII-XIII.

Group XIV, Claim 7, drawn to a food or drink containing a secondary bile acid production inhibitor containing yeast .

Group XV, Claim 7, drawn to a food or drink containing a secondary bile acid production inhibitor containing a yeast Issatchenkia

Group XVI, Claim 7, drawn to a food or drink containing a product which is a secondary bile acid production inhibitor containing a yeast belonging to Hanseniaspora.

Group XVII, Claim 7, drawn to a food or drink containing a product which is a secondary bile acid production inhibitor containing a yeast belonging to Kloeckera.

Group XVIII, claim 7, drawn to a food or drink containing a product which is a secondary bile acid production inhibitor containing a yeast belonging to Kluyveromyces.

Group XIX, claim 7, drawn to a food or drink containing a product which is a secondary bile acid production inhibitor containing a yeast belonging to Pichia.

Group XX, claim 7, drawn to a food or drink containing a product which is a secondary bile acid production inhibitor containing a yeast belonging to Torulaspora.

Art Unit: 1651

Claims 8-14 are not statutory claims and have been withdrawn from consideration.

Group XXI, Claim 17, drawn to a treatment method for inhibiting a secondary bile acid production, comprising administering a yeast.

Group XXII, Claim 18, drawn to a treatment method for inhibiting a secondary bile acid production, comprising administering a yeast *Issatchenkia*

Group XXIII, Claim 18, drawn to a treatment method for inhibiting a secondary bile acid production, comprising administering a yeast *Hanseniaspora*.

Group XXIV, Claim 18, drawn to a treatment method for inhibiting a secondary bile acid production, comprising administering a yeast *Kloeckera*.

Group XXV, claim 18, drawn to a treatment method for inhibiting a secondary bile acid production, comprising administering a yeast *Kluyveromyces*.

Group XXVI, claim 18, drawn to a treatment method for inhibiting a secondary bile acid production, comprising administering a yeast *Pichia*.

Group XXVII, claim 18, drawn to a treatment method for inhibiting a secondary bile acid production, comprising administering a yeast *Torulaspora*.

Group XXVIII, claim 18, drawn to a treatment method for inhibiting a secondary bile acid production, comprising administering more than one yeast-please specify the combination.

Group XXIX, claim 6, drawn to a product which is a secondary bile acid production inhibitor containing a yeast belonging to *Saccharomyces*.

Group XXX, claim 6, drawn to a product which is a secondary bile acid production inhibitor containing a yeast belonging to *Hyphopichia*.

Group XXXI, claim 6, drawn to a product which is a secondary bile acid production inhibitor containing a yeast belonging to *Candida*.

Group XXXII, claim 6, drawn to a product which is a secondary bile acid production inhibitor containing a yeast belonging to *Zygosaccharomyces*.

Art Unit: 1651

Group XXXIII, claim 7, drawn to a food or drink containing a product which is a secondary bile acid production inhibitor containing a yeast belonging to *Saccharomyces*.

Group XXXIV, claim 7, drawn to a food or drink containing a product which is a secondary bile acid production inhibitor containing a yeast belonging to *Candida*.

Group XXXV, claim 7, drawn to a food or drink containing a product which is a secondary bile acid production inhibitor containing a yeast belonging to *Zygosaccharomyces*.

Group XXXVI, claim 18, drawn to a treatment method for inhibiting a secondary bile acid production, comprising administering a yeast belonging to *Saccharomyces*.

Group XXXVII, claim 18 drawn to a treatment method for inhibiting a secondary bile acid production, comprising administering a yeast belonging to *Candida*.

Group XXXVIII, claim 18 drawn to a treatment method for inhibiting a secondary bile acid production, comprising administering a yeast belonging to *Zygosaccharomyces*.

Claim 19 will be examined with the above election of the Group XXII-XXVIII or XXXVI-XXXVIII.

4. The above inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1 in view of the references of record, see AI, which is within the scope of Group IV. Reference to US 4,251,519 which states: "such as brewer's yeast strains, such as *Saccharomyces carlsbergensis*; a lactose utilizing food yeast, *Saccharomyces fragilis*; and strains of *Candida* such as *C. utilis*. *Saccharomyces fragilis* has recently been reclassified to ***Kluyveromyces*** *fragilis*. It has further been discovered that the yeast products can be derived from these various strains of yeast which have been grown on a variety of media. The products from different strains vary in some degree in their composition, but all have the ability to decrease the cholesterol and triglycerides of humans as set forth."

Art Unit: 1651

is evidence of the lack of a single general inventive concept. In addition, The groups of Claim I are not the same set of yeasts as the groups of claim 5.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention, I-XXXVIII to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Art Unit: 1651


Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is (703) 308-2034 and Fax Number** is for applications **Before Final** (703) 872-9306 and **After Final** for applications is 703-872-9307 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
(703) 308-2034
Art Unit 1651
August 7, 2003


Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1651